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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,377	05/03/2001	Gregory Prince	469201-540	8081

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EXAMINER

SCHEINER, LAURIE A

ART UNIT PAPER NUMBER

1648

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

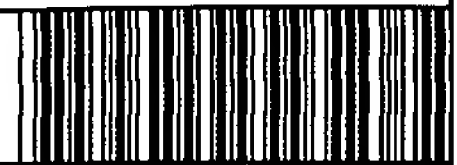
Office Action Summary

Application No.
09/848,377

Applicant(s)
Prince et al.

Examiner
Laurie Scheiner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 31, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above, claim(s) 1-21 and 25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24 and 29-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

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Applicant's election of Group II (claims 22-24) in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Newly presented claims 29-40 will also be examined. Newly submitted claim 28 is directed to an invention that is independent or distinct from the invention originally claimed because the invention elected by applicants is drawn to a method of treating a respiratory disease wherein an anti-viral antibody and a steroid as an anti-inflammatory agent are employed. However, claim 28 differs in scope from the elected invention since an additional anti-bacterial antibody is required. Accordingly, claim 28 is withdrawn from consideration as being directed to a non-elected invention. Claims 1-21 and 25-27 are also withdrawn from consideration. See 37 CFR 1.142(b) and MPEP § 821.03.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Johnson et al. (The Journal of Infectious Diseases, 1999; 180:35-40).

Johnson et al. clearly teach the *in vivo* efficacy of MEDI-493 in the clinical treatment of RSV infection by inhibiting viral replication.

Claims 22, 23, 29-34 and 36-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Prince et al. (US Patent No. 5,290,540).

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Prince et al. clearly teach a method of treating a respiratory disease in an afflicted patient wherein a therapeutically effective amount of an anti-viral neutralizing antibody in a pharmacologically acceptable carrier are employed. Prince et al. additionally teach that an anti-inflammatory agent such a corticosteroid (cortisone) may be additionally employed. The anti-viral antibody is administered in a dosage from 0.1 μ g to 1000 mg/kg body weight of the host, which encompasses the claimed dosage of 5 to 20 mg/kg body weight. Moreover, the steroids of Prince et al. are administered in the dosage range of 0.1 μ g to 1000 mg/kg body weight of the host, which encompasses the claimed dosage of 10 μ g to 1 gram per kg body weight. At column 12, lines 17 to 25, Prince et al. clearly teach concurrent use of an antiviral antibody agent and a corticosteroid. Variations on the treatment protocol are also exemplified.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prince et al. (US Patent No. 5,290,540) in view of Johnson et al. (The Journal of Infectious Diseases, 1999; 180:35-40).

Prince et al. teach as set forth *supra*.

Johnson et al. teach as set forth above.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the MEDI-493 of Johnson et al. in the methods of Prince et al. since Prince et al. clearly teach the superiority of combining administered antiviral and anti-inflammatory agents to

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accelerate clinical therapy. More specifically, Prince et al. clearly teach an *in vivo* method of treating a respiratory disease by the concurrent administering of an anti-RSV antibody and corticosteroid, resulting in accelerated viral clearance and reversal of pulmonary disease.

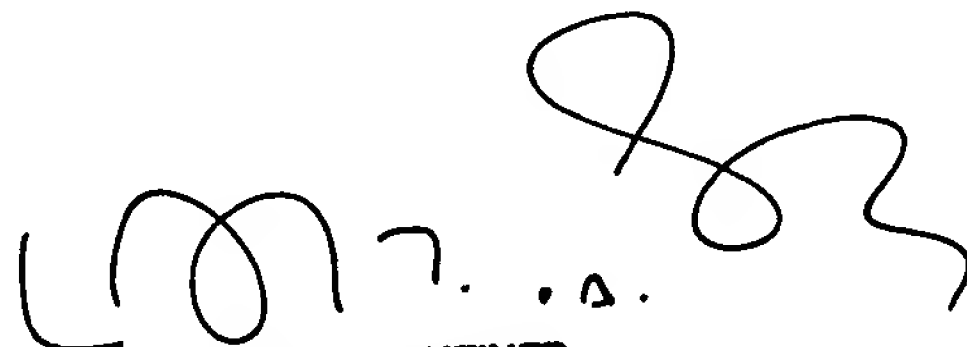
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.



Laurie Scheiner/LAS
November 3, 2003



LAURIE SCHEINER
PRIMARY EXAMINER